



CASE LA0087A CIP

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Sammy G. Duncan Jr. Ph.D.  
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3/12/04  
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF  
SUN ET AL.

APPLICATION NO: 10/780,415

FILED: FEBRUARY 17, 2004

FOR: BICYCLIC MODULATORS OF ANDROGEN RECEPTOR  
FUNCTION

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INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the filing date of the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.


Some of the listed references are of record in parent Application No. 10/438,722 filed May 15, 2003, and copies are available therein. However, applicants are willing to send copies of any or all of these references at the Examiner's request.

Some of the listed references were cited in a search report in a corresponding PCT International application. Copies of these references and the search report are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

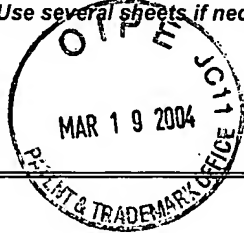
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Sammy G. Duncan Jr. Ph.D.  
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Reg. No. 46,675

Date: 3/17/04

FORM PTO-1449  
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)


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 SUN ET AL.  
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Group

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	3,239,345	3/8/66	Hodge et al.			
	AB	4,036,979	7/19/77	Asato			
	AC	4,411,890	10/25/83	Momany			
	AD	5,179,080	1/12/93	Rothkopf			
	AE	5,488,064	1/30/96	Sher			
	AF	5,491,134	2/13/96	Sher et al.			
	AG	5,541,204	7/30/96	Sher et al.			
	AH	5,612,359	3/18/97	Murugesan			
	AI	5,688,808	11/18/97	Jones et al.			
	AJ	5,688,810	11/18/97	Jones et al.			
	AK	5,693,646	12/2/97	Jones et al.			
	AL	5,693,647	12/2/97	Jones et al.			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	<u>TRANSLATION</u>	
							YES	NO
	AM	WO 89/07110	8/10/89	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 89/07111	8/10/89	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AO	WO 93/04081	3/4/93	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 96/19458	6/27/96	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 97/19086	5/29/97	PCT			<input type="checkbox"/>	<input type="checkbox"/>

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Banz, W.J. et al., "Effects of Soy Protein and Soy Phytoestrogens on Symptoms Associated with Cardiovascular Disease in Rats", Journal of Medicinal Food, Vol. 2, Nos. 3-4, pp. 271-273 (1999)
	AS	Beyler, A.L. et al., "Methods for Evaluating Anabolic and Catabolic Agents in Laboratory Animals", Journal of the American Medical Women's Association, Vol. 23, No. 8, pp. 708-721 (1968)
	AT	Boris, A. et al., "Comparative Androgenic, Myotrophic and Antigonadotrophic Properties of Some Anabolic Steroids", Steroids, Vol. 15, pp. 61-71 (1970)

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	2AA	5,696,127	12/9/97	Jones et al.			
	2AB	5,696,130	12/9/97	Jones et al.			
	2AC	5,696,133	12/9/97	Jones et al.			
	2AD	5,770,615	6/23/98	Cheng et al.			
	2AE	5,776,983	7/7/98	Washburn et al.			
	2AF	6,011,029	1/4/00	Ding et al.			
	2AG	6,040,321	3/21/00	Kim et al.			
	2AH	6,043,265	3/28/00	Murugesan et al.			
	2AI	6,184,231	2/6/01	Hewawasam et al.			
	2AJ						
	2AK						
	2AL						

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	2AM	WO 97/21993	6/19/97	PCT			<input type="checkbox"/>	<input type="checkbox"/>
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	2AO	WO 97/49709	12/31/97	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	2AP	WO 98/22461	5/28/98	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	2AQ	WO 98/25929	6/18/98	PCT			<input type="checkbox"/>	<input type="checkbox"/>

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

	2AR	Bourguet, W. et al., "Crystal Structure of the ligand-binding domain of the human nuclear receptor RXR- $\alpha$ ", Nature, Vol. 375, pp. 377-382 (1995)
	2AS	Brzozowski, A.M. et al., "Molecular basis of agonism and antagonism in the oestrogen receptor", Nature, Vol. 389, pp. 753-758 (1997)
	2AT	Bundgaard, H., "Design and Application of Prodrugs", A Textbook of Drug Design and Development, Harwood Academic Publishers, publ., Krogsgaard-Larsen, P. and Bundgaard, T., eds., pp. 113-191 (1991)

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	3AA	WO 98/38192	9/3/98	PCT			<input type="checkbox"/>	<input type="checkbox"/>
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	3AC	WO 99/00353	1/7/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
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	3AG	WO 99/03848	1/28/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	3AH	WO 99/07692	2/18/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	3AI	WO 99/24416	5/20/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
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	3AS	WO 00/00485	1/6/00	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	3AT	WO 00/01389	1/13/00	PCT			<input type="checkbox"/>	<input type="checkbox"/>
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

4AA	Bundgaard, H., ed., Design of Prodrugs, Elsevier Science Publishers B.V., publ., (table of contents) (1985)
4AB	Chalepakis, G. et al., "Differential Gene Activation by Glucocorticoids and Progestins Through the Hormone Regulatory Element of Mouse Mammary Tumor Virus", Cell, Vol. 53, pp. 371-382 (1988)
4AC	Delaisi, C. et al., "RU54115, A Tight-Binding Aromatase Inhibitor Potentially Useful for the Treatment of Breast Cancer", J. Steroid Biochem. Molec. Biol., Vol. 41, No. 3-8, pp. 773-777 (1992)
4AD	Edwards, J.P. et al., "Nonsteroidal Androgen Receptor Agonists Based on 4-(Trifluoromethyl)-2H-Pyrano[3,2-g]Quinolin-2-One", Bioorganic & Medicinal Chemistry Letters, Vol. 9, pp. 1003-1008 (1999)
4AE	Evans, R.M., "The Steroid and Thyroid Hormone Receptor Superfamily", Science, Vol. 240, pp. 889-895 (1988)
4AF	Gori, Z. et al., "La Ipertrofia Da Testosterone Del Muscolo Elevatore Dell'ano Di Ratto Castrato. - I) Dati Quantitativi", Boll.-Soc. Ital. Biol. Sper., Vol. 42, 1596-1599 (1966)
4AG	Gori, Z. et al., "La Ipertrofia Da Testosterone Del Muscolo Elevatore Dell'ano Di Ratto Castrato. - II) Osservazioni Al Microscopio Elettronico", Boll.-Soc. Ital. Biol. Sper., Vol. 42, 1600-1601 (1966)
4AH	Grese, T.A. et al., "Molecular determinants of tissue selectivity in estrogen receptor modulators", Proc. Natl. Acad. Sci. USA, Vol. 94, pp. 14105-14110 (1997)
4AI	Hamann, L.G. et al., "Discovery of a Potent, Orally Active, Nonsteroidal Androgen Receptor Agonist: 4-Ethyl-1,2,3,4-tetrahydro-6-(trifluoromethyl)-8-pyridono[5,6-g]-quinoline (LG121071)", J. Med. Chem., Vol. 42, pp. 210-212 (1999)
4AJ	Hamann, L.G. et al., "Synthesis and Biological Activity of a Novel Series of Nonsteroidal, Peripherally Selective Androgen Receptor Antagonists Derived from 1,2-Dihydropyridono [5,6-g] quinolines", J. Med. Chem., Vol. 41, pp. 623-639 (1998)
4AK	Heiser, W.C., "Optimizing Electroporation Conditions for the Transformation of Mammalian Cells", Methods in Molecular Biology, Vol. 130, pp. 117-134 (2000)
4AL	Hempstock, J. et al., "Inhibition of Growth of Primary Human Prostate Cells by Phytoestrogens", Journal of Medicinal Food, Vol. 2, Nos. 3-4, pp. 243-246 (1999)
4AM	Hershberger, L.G. et al., "Myotrophic Activity of 19-Nortestosterone and Other Steroids Determined by Modified Levator Ani Muscle Method", P.S.E.B.M., Vol. 83, pp. 175-180 (1953)
4AN	Hiraoka, D. et al., "Inhibitory and Stimulatory Effects of Glucocorticoid on Androgen-induced Growth of Murine Shionogi Carcinoma 115 <i>in Vivo</i> and in Cell Culture", Cancer Research, Vol. 47, pp. 6560-6564 (1987)

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5AA	Imakura, Y. et al., "Regioselective Cleavage Reaction of the Aromatic Methylenedioxy Ring. V. Cleavage with Sodium Alkoxides-Alcohols, Potassium <i>tert</i> -Butoxide-Alcohols, Dimethyl Anion-Methyl Alcohol, Metallic Sodium-Alcohols, etc., Chem. Pharm. Bull. Vol. 40, No. 7, pp. 1691-1696 (1992)
5AB	Johannsson, G. et al., "Growth Hormone Treatment of Abdominally Obese Men Reduces Abdominal Fat Mass, Improves Glucose and Lipoprotein Metabolism, and Reduces Diastolic Blood Pressure", Journal of Clinical Endocrinology and Metabolism, Vol. 82, No. 3, pp. 727-734 (1997)
5AC	Kakigami, T. et al., "Synthesis and Structure-Activity Relationship of 3-Substituted Benzamide, Benzo[b]furan-7-carboxamide, 2,3-Dihydrobenzo[b]furan-7-carboxamide, etc.", Chem. Pharm. Bull., Vol. 46, No.1, pp. 42-52 (1998)
5AD	Milata, V. et al., "Simple and Convenient Procedure for the Preparation of 1-methyl-4-nitrobenzimidazole", Org. Prep. Proced. Int., Vol. 25, No. 6, pp. 703-704 (1993)
5AE	Minesita, T. et al., "An Androgen-dependent Mouse Mammary Tumor", Cancer Research, Vol. 25, pp. 1168-1175 (1965)
5AF	Navone, N.M. et al., "Establishment of Two Human Prostate Cancer Cell Lines Derived from a Single Bone Metastasis", Clinical Cancer Research, Vol. 3, pp. 2493-2500 (1997)
5AG	Neri, R. et al., "A Biological Profile of a Nonsteroidal Antiandrogen, SCH 13521 (4'-Nitro-3'-Trifluoromethylisobutyranilide)", Endo, Vol. 91, No. 2, pp. 427-437 (1972)
5AH	Okuda, Y. et al., "Testosterone Dependant Regulation of the Enzymes Involved in DNA Synthesis in the Rat Ventral Prostate", The Journal of Urology, Vol. 145, pp. 188-191 (1991)
5AI	Quella, S.K. et al., "Evaluation of Soy Phytoestrogens for the Treatment of Hot Flashes in Breast Cancer Survivors: A North Central Cancer Treatment Group Trial", Journal of Clinical Oncology, Vol. 18, No. 5, pp. 1068-1074 (2000)
5AJ	Regal, J.F. et al., "Dietary Phytoestrogens Have Anti-Inflammatory Activity in a Guinea Pig Model of Asthma", P.S.E.B.M., Vol. 223, pp. 372-378 (2000)
5AK	Rodbard, D., "Chapter 3: Mathematics and Statistics of Ligand Assays: An Illustrated Guide", Ligand Assay, Masson Publishing USA, Inc., publ., J. Langan et al., eds, pp. 45-101 (1981)
5AL	Schuur, E.R. et al., "Prostate-Specific Antigen Expression Is Regulated by an Upstream Enhancer", The Journal of Biological Chemistry, Vol. 271, No. 12, pp. 7043-7051 (1996)
5AM	Shiau, A.K. et al., "The Structural Basis of Estrogen Receptor/Coactivator Recognition and the Antagonism of This Interaction by Tamoxifen", Cell, Vol. 95, pp. 927-937 (1998)
5AN	Smigel, K., "Breast Cancer Prevention Trial Shows Major Benefit, Some Risk", Journal of the National Cancer Institute, Vol. 90, No. 9, pp. 647-648 (1998)

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	6AA	Suzuki, T. et al., "Effects of Antiandrogens on Growth of Androgen-Dependent Mouse Mammary Tumor (Shionogi Carcinoma 115) <i>In Vivo</i> and <i>In Vitro</i> ", J. Steroid Biochem. Molec. Biol., Vol. 37, No. 4, pp. 559-567 (1990)
	6AB	Tanenbaum, D.M. et al., "Crystallographic comparison of the estrogen and progesterone receptor's ligand binding domains", Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 5998-6003 (1998)
	6AC	Vegeto, E. et al., "The Mechanism of RU486 Antagonism is Dependent on the Conformation of the Carboxy-Terminal Tail of the Human Progesterone Receptor", Cell, Vol. 69, pp. 703-713 (1992)
	6AD	Venable, J.H., "Constant Cell Populations in Normal, Testosterone-Deprived and Testosterone-stimulated Levator Ani Muscles", Am. J. Anat., Vol. 119, pp. 263-270 (1966)
	6AE	Wermuth, C.G. et al., "Designing Prodrugs and Bioprecursors I: Carrier Prodrugs", The Practice of Medicinal Chemistry, Academic Press, publ., Wermuth, C.G., ed., pp. 671-696 (1996)
	6AF	
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